



Food and Drug Administration
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August 29, 2014

Microport Orthopedics, Incorporated
Ms. Caroline Fryar
Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

Re: K140735

Trade/Device Name: EVOLUTION® MP CS/CR Porous Femur
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated
Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: August 5, 2014
Received: August 6, 2014

Dear Ms. Fryar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K140735

Device Name

EVOLUTION® MP CS/CR Porous Femur

Indications for Use (Describe)

The EVOLUTION® MP CS/CR Porous Femur is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1. Non-inflammatory degenerative joint disease: including osteoarthritis, traumatic arthritis, or avascular necrosis
2. Inflammatory degenerative joint disease, including rheumatoid arthritis;
3. Correction of functional deformity
4. Revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

The EVOLUTION® MP CS/CR Porous Femur is for uncemented use only.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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EVOLUTION® MP CS/CR Porous Femur
Traditional 510(k)
Tab 005: 510(k) Summary of Safety and Effectiveness



510(k) Summary of Safety and Effectiveness

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the EVOLUTION® MP CS/CR Porous Femur and EVOLUTION® Adaptive CS Inserts.

Submitted by: MicroPort Orthopedics Inc.
5677 Airline Rd, Arlington TN, 38002
Phone: 866-872-0211
Fax: 855-446-2247

Date: August 27, 2014

Contact Person: Caroline Fryar
Regulatory Affairs Specialist

Proprietary Name: EVOLUTION® MP CS/CR Porous Femur
EVOLUTION® Adaptive CS and PS Inserts

Common Name: Cementless Femoral Component
Tibial Insert

Classification Name and Reference: 21 CFR888.3565 Knee joint Patellofemorotibial metal/Polymer
Porous-Coated Uncemented prosthesis

21 CFR 888.3560 Knee joint patellofemorotibial
polymer/metal/polymer semi-constrained cemented prosthesis
Class II

Subject Product Code and Panel Code: Orthopedics/87/MBH
Orthopedics/87/MBH, JWH

Predicate Devices: EVOLUTION® MP CS/CR Non-Porous Femur (K093552, K102380)
ADVANCE® Porous Femur (K061223)

EVOLUTION® Adaptive CS Insert (K113325)
EVOLUTION® Adaptive PS Insert (K131679)
ADVANCE® Spiked Porous Tibial Base (K063128)

EVOLUTION® MP CS/CR Porous Femur
Traditional 510(k)
Tab 005: 510(k) Summary of Safety and Effectiveness

DEVICE INFORMATION

A. Intended Use

The EVOLUTION® MP CS/CR Porous Femur is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1. Non-inflammatory degenerative joint disease: including osteoarthritis, traumatic arthritis, or avascular necrosis
2. Inflammatory degenerative joint disease, including rheumatoid arthritis;
3. Correction of functional deformity
4. Revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

The EVOLUTION® MP CS/CR Porous Femur is for uncemented use only.

B. Device Description

The EVOLUTION® MP CS/CR Porous Femur is a line extension of the EVOLUTION® MP Total Knee System product line. The device is a distal femoral knee joint replacement implant, and is porous coated for cementless fixation. The design features are summarized below:

- Manufactured from Cobalt Chrome Alloy
- Inner surfaces coated with porous beads for cementless fixation
- Available in sizes 1-8, left and right
- Compatible with 510(k) cleared EVOLUTION® Tibial Inserts and ADVANCE® Patellae

The tibial compatibility for the EVOLUTION® Adaptive CS and PS Tibial Inserts is being expanded to include all 510(k) cleared ADVANCE® II Tibial Bases. The subject designs and indications remain identical according to their respective 510(k) clearances.

C. Substantial Equivalence Information

The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The indications for use are identical to the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices, as well. The safety and effectiveness of the subject devices are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

EVOLUTION® MP CS/CR Porous Femur

Traditional 510(k)

Tab 005: 510(k) Summary of Safety and Effectiveness

D. Nonclinical Testing

The subject EVOLUTION® MP CS/CR Porous Femur was evaluated for comparison to the predicate femur cleared in K093552, and was found not to create a worst-case with respect to intrinsic femoral component strength. The testing concluded that the subject femoral component performs as well or better than the predicate device, and can be expected to perform well under normal physiological loading conditions.

E. Clinical Testing

Clinical data was not provided for the subject devices.

F. Conclusion

The design features of the subject devices are substantially equivalent to the predicate devices. The instruments and materials remain identical to those cleared under K093552, K102380, K113325, and K131679. The safety and effectiveness of the subject devices is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.